(NSCLC). Using data from the SEER-Medicare cancer registry, we examined trends in use, outcomes, and costs of care for NSCLC patients receiving chemotherapy in community settings from 1994–2001. **METHODS:** Patients were included if they were diagnosed with locally advanced or metastatic (TNM stages IIIb and IV) NSCLC between 1 January 1994 and 31 December 2001. Patients were stratified based on initial chemotherapy agent(s) used. Cox proportional hazards models were used to compare survival as a function of initial chemotherapy regimen, controlling for age, sex, race, noncancer comorbidity, stage at diagnosis, SEER region, and receipt of cancer-related surgery or radiation therapy in the first 3 months following diagnosis. Lifetime medical costs were calculated for each chemotherapy group using the Kaplan Meier sample average estimator. **RESULTS:** A total of 14,875 met inclusion criteria, 7411 (49.8%) stage IIIb and 7464 (50.2%) stage VI at diagnosis. Chemotherapy use in the first 3 months following diagnosis increased from 21% to 43% of those diagnosed over the observation period ($p < 0.01$). Persons >= 75 (OR = 0.91), females (OR = 0.87), African Americans (OR = 0.49) and those with >1 comorbidity (OR = 0.84) were significantly less likely to receive chemotherapy. Multivariate Cox proportional hazards models demonstrated that survival was inferior for those not receiving a platinum agent ($p < 0.01$). Lifetime medical care costs differed significantly among regimens [mean (std. dev.)]: no chemotherapy $27,833 (372); cisplatin or carboplatin alone $128,179 (11,968); cisplatin or carboplatin plus taxane $78,451 (2,898); cisplatin/carboplatin + other agent not taxane $68,173 (2663) single agent or doublet excluding cisplatin or carboplatin $55,959 (2331). **CONCLUSIONS:** Chemotherapy use for advanced NSCLC has increased substantially. Platinum containing regimens (recommended by guidelines) are superior. Some combinations are more costly but do not offer improved survival.

**PCN8**

### OUTCOMES AND COSTS OF SURROGATE END-POINTS (SES) AND BIOMARKERS IN PHASE I ONCOLOGY CLINICAL TRIALS

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**OBJECTIVES:** Targeted therapies, functional imaging and translational research have enabled utilization of a new endpoint in phase I oncology trials, known as Surrogate Endpoints (SEs) or biomarkers. Investigators hope that SEs will improve the efficiency of drug-development. However, whether SEs can substitute for traditional endpoints is unknown. The role of SEs in drug selection, target validation, dosing and schedule is not defined. **METHODS:** We analyzed phase I single-agent abstracts in PASCO from 1992 to 2002 that included at least one SE. Subsequent publications were analyzed based on the primary SE. Drugs were classified as cytotoxic, biologic, or targeted and SEs classified by their technology (imaging, blood biomarkers or advanced histology). We designed 4 questions to evaluate the role of SEs, beginning with: "Did the SE help . . . : 1) ". . . determine the dose for phase II?"; 2) ". . . in finding the schedule?"; 3) ". . . with the author's conclusions?"; and 4) ". . . validate that the target was affected?". McNemar's and chi-square tests compared the utility of SEs across these questions and across drug classes, respectively. We also related the budgets of 18 institutional trials to their number of SEs. **RESULTS:** Of 74 trials, 57% tested biologics, 24% small molecules, 14% cytotoxic and 5% other. According to technology: 68% were blood studies, 24% histologic analysis, and 7% imaging. The frequency of "yes" for the 4 questions was 15%, 16%, 38%, and 62%, respectively ($p < 0.001$ between questions), without differences between classes. The budgeted cost of adding a SE was US$6675 per patient. **CONCLUSIONS:** SEs modestly aided in defining dose and schedule for future studies and in the overall drug-development process. They helped in validating that the therapy affected the intended target. Better preclinical evaluation of SEs may enhance their utility. Further research should help define how best to incorporate SEs into trial design.

**PCN9**

### COST EFFECTIVENESS OF ADDING BISPHOSPHONATES TO THE NON-SURGICAL ANDROGEN DEPRIVATION THERAPY FOR FRACTURE REDUCTION IN PATIENTS WITH NON-METASTATIC PROSTATE CANCER

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**OBJECTIVES:** Prostate Cancer patients using Androgen Deprivation Therapy (ADT) are considered at a higher risk for osteoporotic fractures due to excessive loss of bone mineral density (BMD). This study measured the incremental Cost Effectiveness (CE) of adding bisphosphonates to ADT based on QALYs gained. **METHODS:** A Markov model of fracture-risk associated with osteoporosis in patients with non-metastatic prostate cancer was developed to compare the incremental CE of adding pamidronate or zoledronic acid to ADT. Literature-based estimates of costs of treating osteoporotic fractures and average wholesale prices of bisphosphonates were used. Disutilities published by the National Osteoporotic Foundation for the first and subsequent year following an osteoporotic fracture were used to measure effectiveness of prescribing bisphosphonates. Robustness of assumptions was tested using deterministic and stochastic sensitivity analyses. **RESULTS:** The Markov analyses yielded total incremental cost of $17,009.40 for ADT + pamidronate and of $25,838.90 for ADT + zoledronic acid over ADT only option. Adding pamidronate resulted in a gain of 0.0128 QALYs at a marginal CE of $1,327,746 as compared to zoledronic acid which resulted in a gain of 0.015 QALYs at a marginal CE of $1,722,593. Monte Carlo simulation as well as one-way and two-way sensitivity analyses indicated robustness of the key assumptions such as probability of fracture, probability of death due to hip fracture and discount rate. **CONCLUSIONS:** In case of reducing the fracture-risk in non-metastatic prostate cancer patients using bisphosphonates resulted in nominal gain in QALYs at a very high marginal CEs for both drugs.

**PCN10**

### THE COST-EFFECTIVENESS OF METHYL AMINOLEVULINATE PHOTODYNAMIC THERAPY (MAL-PDT) FOR BASAL CELL CARCINOMA

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**OBJECTIVES:** Basal cell carcinoma (BCC) is a common malignant tumour, usually treated with surgery though the cosmetic appearance of the treated lesions can be poor. Methyl aminolevulinate cream is the first topical PDT therapy licensed in the UK for superficial, or mid-face, large or recurrent nodular BCC and can be considered for lesions unsuitable for surgery. The aim of this evaluation was to assess the cost-effectiveness of MAL-PDT versus excision. **METHODS:** Clinical outcomes were from a comparative trial of nodular BCC. The clinical response for MAL-PDT from a non-comparative trial of primary superficial BCC (Horn et al, in press) was also used to reflect the subgroup most likely to be treated with MAL-PDT. Lesion reoccurrence was derived from published literature and an expert Delphi panel provided resource use. The NHS perspective was taken and only direct costs were considered. Decision analysis was used with MAL-PDT or excision as first line therapy and, if no lesion